IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Paent Appeals and Interferences

Applicant: Nancy Auestad et al.

USSN: 10/625,420

Filed: July 23, 2003

Title: **Appetite Control Method**

Docket No.: 6960USP1
Art Unit: 1614
Examiner: Leslie A. Royds

I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Commissioner for Patents, Alexandria, VA, 22313, on the date shown below.

Wendy Detwiler 1-27-06
Wendy Detwiler Date

APPEAL BRIEF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

This Appeal Brief is submitted in response to the September 29, 2005 Final Office Action in the above-entitled application. A Notice of Appeal was submitted on October 10, 2005. A Petition for Extension of Time and authorization to charge fees related to this submission are included in the accompanying transmittal. This brief includes the following items, with headings, presented in the following order:

I. Real party in interest

II. Related appeals and interferences

III. Status of claims

IV. Status of amendments

V. Summary of claimed subject matter

VI. Grounds of rejection to be reviewed on appeal

VII. Argument

VIII. Claims appendix

IX. Evidence appendix

X. Related proceedings appendix

XI. Conclusion

I. REAL PARTY IN INTEREST

The real party in interest is Abbott Laboratories, Abbott Park, Illinois.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals, judicial proceedings, or interferences.

III. STATUS OF CLAIMS

Claims 1-29 were originally filed in this application. Claims 1-29 remain pending, each of which stands rejected and is now on appeal.

IV. STATUS OF AMENDMENTS

An Amendment under 37 C.F.R. §1.116 was submitted on October 10, 2005, and subsequently entered in an Advisory Action dated November 7, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1-11 and 27-29 are methods for decreasing, reducing, or modulating the appetite of a human or other mammal comprising administering an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease, reduce, or modulate the appetite of said mammal, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

Claims 12-17 are methods for antagonizing the CB_1 cannabinoid receptor in the brain of a mammal comprising enterally administering an amount of long-chain n-3 polyunsaturated fatty acid effective to antagonize the CB_1 cannabinoid receptor activity in the brain, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

Claims 18-23 are methods for decreasing the incidence of obesity or overweight status in a population of mammals comprising enterally administering to at least some members of said population an amount of long-chain n-3 polyunsaturated fatty acid effective to modulate negatively the appetite of said mammal, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

Claims 24-26 are methods for increasing serum leptin levels of a human or other mammal, said method comprising administering an effective amount of a long-chain n-3 polyunsaturated fatty acid to increase postprandial serum leptin levels, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Are claims 1-29 anticipated by WO 02/00042 (Jandacek) under 35 U.S.C. §102?

2. Are claims 1-29 unpatentable under 35 U.S.C. §103(a) as being obvious over WO 02/00042 (Jandacek)?

VII. ARGUMENTS

Grounds of Rejection 1

Claims 1-29 stand rejected under 35 U.S.C. §102 as being anticipated by WO 02/00042 (Jandacek). Jandacek discloses compositions comprising satiety agents selected from the group consisting of long chain fatty acids and their non-glyceryl esters, hydrolyzable in the presence of gastro-intestinal enzymes, wherein the satiety agent releases in the stomach (see Jandacek at page 3, lines 27-33).

Jandacek fails to disclose the effective use of triacylglyeryl esters of long-chain n-3 polyunsaturated fatty acid as satiety agents. Jandacek repeatedly specifies the use of non-glycerol esters as satiety agents (see Jandacek at p. 4, line 10; p. 5, lines 4, 11-12, 24, and 26; p. 7, line 3). All claims now on appeal are limited to the use triacylglyeryl esters - specifically, long-chain polyunsaturated n-3 fatty acids administered in the form of a triacylglycerol.

The Examiner contends, however, that Jandacek discloses the use of triacylglyeryl esters as non-preferred embodiments (see Sept. 29, 2005 Office Action at p. 5), and therefore anticipates the present claims. To support this

rejection, the Examiner relies upon that portion of the Jandacek reference that states:

> "Essentially all long chain fatty acids in the diet are ingested in the form of triacylglycerols ... ingested fatty acids from triacylglycerols are first distributed throughout the body in the form of triacylglycerols. Little of these reach the liver in the form of long chain non-esterified fatty acids during the course of the meal and thus influence food intake." Jandacek, p. 5, lines 4-15.

Applicants submit that the above-statement does not teach triacylglycerols for use as satiety agents, even as non-preferred embodiments. Instead, it teaches that triacylglycerols are not effective as satiety agents. The Jandacek reference, taken as a whole, further supports this, by consistently and repeatedly disclosing that these triacylglycerol esters do not affect satiety:

> "Intravenous administration of a triacylglycerol emulsion (Intralipid) failed to reduce total caloric intake in several studies ..." Jandacek at p.1, lines 33 and 34.
>
> "Pre-meals of triacylglycerols in yogurt also fail to reduce total caloric intake (meal plus pre-meal) at subsequent meals." Jandacek at p.2, lines 2-4.
>
> "Greenberg et al. have shown that duodenally infused emulsions of triacylglycerol and linoleic acid reduce total caloric intake in a sham feeding rat model, whereas ileal infusions do not ..." Jandacek at p.2, lines 18-20.
>
> "These investigators also demonstrated that pre-meals of triacylglycerol fail to suppress total caloric intake in rats constrained to over seven hours of feeding..." Jandacek at p. 2, lines 33 and 34.
>
> "... Cox et al. have shown that jejunally infused neat linoleic acid or oleic acid ... will significantly reduce total daily caloric intake in rats, whereas a long chain triacylglycerol (corn oil) will not." Jandacek at p. 3, lines 6-8. "

In view of the foregoing, Applicants submit that Jandacek fails to disclose the effective use of triacylglycerol esters of long-chain n-3 polyunsaturated fatty acids to affect appetite, a key limitation in claims 1-11 and 27-29, now on appeal.

The Jandacek reference, therefore, cannot properly support a rejection of these claims as anticipated under 35 U.S.C. §102.

Applicants also submit that claims 12-26, also on appeal, are likewise not anticipated by the Jandacek reference because they too are limited to the use of the same triacylglycerol esters recited in claims 1-11 and 27-29.

Grounds of Rejection 2

Claims 1-11 and 18-23 stand rejected under 35 U.S.C. §103(a) as unpatentable over WO 02/00042 (Jandacek). The Jandacek reference is summarized above. In maintaining this rejection, the Examiner states:

> "While Jandacek et al. acknowledges that a triacylglycerol may not have the same level of efficacy as a non-glycerol ester of a long-chain fatty acid, such does not amount to an express statement that the use of triacylglycerols will have absolutely no effect whatsoever on dietary intake. In light of such, the skilled artisan would have reasonably expected that the administration of triacylglycerol would show some degree of efficacy in modulating food consumption. Applicant's data merely supports the conclusion that the skilled artisan would have expected and does not support the position that such results would have been unexpected or out of the ordinary." Sept. 29, 2005 Office Action, p. 8

Applicants submit, however, that the above-statement fails to accurately characterize the Jandacek disclosure. Nowhere does Jandacek "acknowledge" that triacylglycerols may not have the same level of efficacy as non-glycerol esters. Instead, Jandacek repeatedly discloses that triacylglycerols are not effective as satiety agents:

> "Intravenous administration of a triacylglycerol emulsion (Intralipid) failed to reduce total caloric intake in several studies ..." Jandacek at p.1, lines 33 and 34.
>
> "Pre-meals of triacylglycerols in yogurt also fail to reduce total caloric intake (meal plus pre-meal) at subsequent meals." Jandacek at p.2, lines 2-4.
>
> "Greenberg et al. have shown that duodenally infused emulsions of triacylglycerol and linoleic acid reduce total caloric intake in a sham feeding rat model, whereas ileal infusions do not ..." Jandacek at p.2, lines 18-20.

> "These investigators also demonstrated that pre-meals of triacylglycerol fail to suppress total caloric intake in rats constrained to over seven hours of feeding..." Jandacek at p. 2, lines 33 and 34.
>
> "... Cox et al. have shown that jejunally infused neat linoleic acid or oleic acid ... will significantly reduce total daily caloric intake in rats, whereas a long chain triacylglycerol (corn oil) will not." Jandacek at p. 3, lines 6-8. "
>
> "Essentially all long chain fatty acids in the diet are ingested in the form of triacylglycerols ... ingested fatty acids from triacylglycerols are first distributed throughout the body in the form of triacylglycerols. Little of these reach the liver in the form of long chain non-esterified fatty acids during the course of the meal and thus influence food intake." Jandacek at p. 5, lines 4-15.

Moreover, Jandacek repeatedly defines his invention as being limited to satiety agents selected from the group consisting of long chain fatty acids and their non-glyceryl esters, hydrolyzable in the presence of gastro-intestinal enzymes, wherein the satiety agent releases in the stomach (see Jandacek at page 3, lines 27-33). This clearly directs the skilled artisan away from the use of glycerol esters (i.e., acylglycerol esters) as satiety agents.

Jandacek teaches away from the methods of the present invention as it directs the skilled artisan away from the use of acylglycerol esters as satiety agents. Jandacek discloses that triacylglycerols are hydrolyzed in the small intestine rather than the stomach (see Jandacek at page 5, lines 4-6) and will thus have little effect on food intake (see page 5, lines 12-15). Jandacek also discloses that optional glyceryl and multiglyceryl fatty acid esters should not include those that form 2-monoacylglyerols " (see Jandacek at page 8, lines 18-20 and 26-27). Jandacek also teaches that triacylglycerols hydrolyze and form 2-monoacylglycerols in the small intestine (see Jandacek at page 5, lines 4-7).

Jandacek therefore teaches away from the triacylglycerol limitations in the present claims (i.e., long-chain n-3 polyunsaturated fatty acids from triacylglycerol esters), because these triacylglycerols form 2-monoacylglycerols in the small intestine, something that is to be avoided according to Jandacek.

Applicants also submit that the data in support of the claimed methods are unexpected, especially in view of the Jandacek reference. Contrary to Jandacek, Applicants have found that certain dietary n-3 long chain polyunsaturated fatty

acids (from triacylglycerols) do indeed affect food intake. Applicants conducted an animal study comparing rat milk formulas containing (1) no DHA or AA, or (2) 2.5% DHA and no AA, (3) no DHA and 2.5% AA, or (4) 2.5% DHA and 2.5% AA. The DHA oil in the study was DHASCO™ oil (Martek Biosciences Corp.) and the AA oil was ARASCO™ oil (Martek Biosciences Corp.), both of which are triacylglycerols of either DHA or AA fatty acids (see Applicants' Specification at p. 44).

The results of the animal study included a showing that DHA oil (triacylglycerol of docosahexaenoic acid, 22:6 n-3) fed postnatally to rat pups from days 6-18 resulted in a 12% decrease in food consumption following food restriction on postnatal day 19 (see Applicants' Specification at p. 51, lines 1-8) This particular finding is in contrast to the Jandacek et al. reference, which teaches that such triacylglycerols are not effective in reducing caloric intake.

In view of the foregoing, Applicants submit that Jandacek fails to teach or suggest the effective use of triacylglycerol esters of long-chain n-3 polyunsaturated fatty acids to affect appetite, a key limitation in all claims now on appeal. The Jandacek reference, therefore, cannot properly support a rejection of these claims as unpatentably obvious under 35 U.S.C. §103

VIII. CLAIMS APPENDIX

The text of the claims on appeal is:

Listing of Claims

1. (previously presented) A method for decreasing the appetite of a mammal comprising enterally administering to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

2. (previously presented) The method according to claim 1 wherein said long-chain n-3 polyunsaturated fatty acid comprises docosahexaenoic acid.

3. (previously presented) The method of claim 2 wherein said long-chain n-3 polyunsaturated fatty acid is administered independent of arachidonic acid.

4. (previously presented) The method according to claim 1 wherein said long-chain n-3 polyunsaturated fatty acid is administered during a growth phase prior to or in conjunction with an appetite-impacting stimulus.

5. (previously presented) The method according to claim 1 wherein said long-chain n-3 polyunsaturated fatty acid is administered to an infant in a daily amount of 8 to 396 mg/kg body weight.

6. (previously presented) The method according to claim 1 wherein said long-chain n-3 polyunsaturated fatty acid is administered to a child or an adult in a daily amount of 84 to 15,832 mg.

7. (previously presented) A method for modulating the appetite of a mammal comprising enterally administering to said mammal an amount of long-chain n-3 polyunsaturated fatty acid and an amount of long-chain n-6 polyunsaturated fatty acid in relative amounts effective to modulate the appetite of said mammal,

wherein the polyunsaturated fatty acids are administered in the form of a triacylglycerol.

8. (previously presented) The method according to claim 7 wherein said long-chain n-3 polyunsaturated fatty acid comprises docosahexaenoic acid and said long-chain n-6 polyunsaturated fatty acid comprises arachidonic acid.

9. (previously presented) The method according to claim 7 wherein said long-chain n-3 polyunsaturated fatty acid is administered during a growth phase prior to or in conjunction with an appetite-impacting stimulus.

10. (previously presented) The method according to claim 7 wherein said long-chain n-3 polyunsaturated fatty acid is administered to an infant in a daily amount of 8 to 396 mg/kg body weight.

11. (previously presented) The method according to claim 7 wherein said long-chain n-3 polyunsaturated fatty acid is administered to a child or an adult in a daily amount of 84 to 15,832 mg.

12. (previously presented) A method for antagonizing the CB_1 cannabinoid receptor in the brain of a mammal comprising enterally administering to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to antagonize the CB_1 cannabinoid receptor activity in the brain of said mammal, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

13. (previously presented) The method according to claim 12 wherein said long-chain n-3 polyunsaturated fatty acid comprises docosahexaenoic acid.

14. (previously presented) The method of claim 12 wherein said long-chain n-3 polyunsaturated fatty acid is administered independent of arachidonic acid.

15. (previously presented) The method according to claim 12 wherein said long-chain n-3 polyunsaturated fatty acid is administered during a growth phase prior to or in conjunction with an appetite-impacting stimulus.

16. (previously presented) The method according to claim 12 wherein said long-chain n-3 polyunsaturated fatty acid is administered to an infant in a daily amount of 8 to 396 mg/kg body weight.

17. (previously presented) The method according to claim 12 wherein said long-chain n-3 polyunsaturated fatty acid is administered to a child or an adult in a daily amount of 84 to 5,832 mg.

18. (previously presented) A method for decreasing the incidence of obesity or overweight status in a population of mammals comprising enterally administering to at least some members of said population an amount of long-chain n-3 polyunsaturated fatty acid effective to modulate negatively the appetite of said mammal, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

19. (previously presented) The method according to claim 18 wherein said long-chain n-3 polyunsaturated fatty acid comprises docosahexaenoic acid.

20. (previously presented) The method of claim 18 wherein said long-chain n-3 polyunsaturated fatty acid is administered independent of arachidonic acid.

21. (previously presented) The method according to claim 18 wherein said long-chain n-3 polyunsaturated fatty acid is administered during a growth phase prior to or in conjunction with an appetite-impacting stimulus.

22. (previously presented) The method according to claim 18 wherein said long-chain n-3 polyunsaturated fatty acid is administered to an infant in a daily amount of 8 to 396 mg/kg body weight.

23. (previously presented) The method according to claim 18 wherein said long-chain n-3 polyunsaturated fatty acid is administered to a child or an adult in a daily amount of 84 to 15,832 mg.

24. (previously presented) A method for increasing serum leptin levels of a human or other mammal, said method comprising administering to the human or other mammal an effective amount of a long-chain n-3 polyunsaturated fatty acid to increase postprandial serum leptin levels, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

25. (previously presented) The method of claim 24 wherein the long-chain n-3 polyunsaturated fatty acid comprises docosahexaenoic acid.

26. (previously presented) The method of claim 24 wherein the long-chain n-3 polyunsaturated fatty acid is administered to a child or an adult in a daily amount of from 84 to 15,832 mg.

27. (previously presented) A method for reducing the appetite of a human or other mammal, said method comprising administering to the human or other mammal an effective amount of long-chain n-3 polyunsaturated fatty acid to increase serum leptin levels, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol.

28. (previously presented) The method of claim 27, wherein the long-chain n-3 polyunsaturated fatty acid comprises docosahexaenoic acid.

29. (previously presented) The method of claim 27 wherein the long-chain n-3 polyunsaturated fatty acid is administered to a child or adult in a daily amount of from 84 to 15,832 mg.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None

XI. CONCLUSION

Accordingly, Applicants request the honorable Board of Appeals and Interferences reverse the Examiner's rejections and remand with directions to allow the above-entitled Application to issue with Claims 1-29.

Respectfully submitted,

By _____

William J. Winter
Attorney for Applicant
Registration No. 36,060

Abbott Laboratories
Department 108140/S1
625 Cleveland Avenue
Columbus, OHIO 43215-1724
Phone (614) 624-5686; Fax. (614) 624-3074